SECTION OF SPINAL SURGERY
THE NEUROSURGICAL SERVICES

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 16, 1999

RE: Docket No. 97N-484S

Dear Sirs:

I am writing to express my vehement opposition to the regulation referenced **Docket No. 97N-484S** , in which it is proposed that the FDA regulate the use of allograft bone used in spinal surgery as a medical device.

Allograft and autograft bone has been used successfully since the late 1800's by spinal surgeons to augment fusion and stabilize the spine. Grafting with allograft requires individual surgical judgment as to graft type, size, contour, and shaping, depending upon its application. Using allograft is considered standard of care in many interbody spinal fusion procedures. Classifying and regulating its use as a device would constitute regulation of a standard, time honored practice of medicine, which is not a function of the FDA. I am therefore in clear opposition of this proposal.

Sincerely,

Eric J. Woodard, MD

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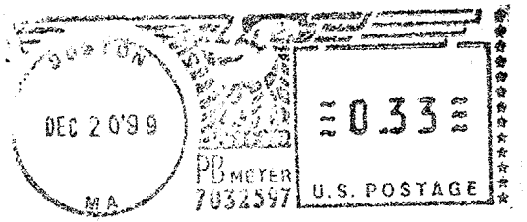

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